USAARL Report No. 2012-02

Clinical Assessment of the Noise Immune Stethoscope aboard a U.S. Navy Carrier

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Warfighter Health Division

November 2011

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REPORT DOCUMENTATION PAGE

Form Approved
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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
7-11-2011	Final	

4. TITLE AND SUBTITLE

Clinical Assessment of the Noise Immune Stethoscope aboard a U.S. Navy Carrier

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

U.S. Army Aeromedical Research Laboratory
P.O. Box 620577
Fort Rucker, AL 36362

8. PERFORMING ORGANIZATION REPORT NUMBER

USAARL 2012-02

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-501

10. SPONSOR/MONITOR'S ACRONYM(S)

USAMRAA

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This study was conducted in support of advanced technology development for clinical auscultation in high noise environments. The diagnostic performance of the Noise Immune Stethoscope (NIS) was assessed by user-clinicians in a deployed environment. The NIS is a hybrid dual function stethoscope with both electromechanical acoustic (passive) and ultrasound Doppler (active) modes. Data were collected over a 7 month operational deployment by the medical department of a Nimitz-class aircraft carrier. Eighteen observations were made with both modes for cases of adventitious cardiopulmonary sounds and intubation integrity. Overall, users evaluated the device to be moderately helpful in making clinical diagnosis and decisions in noisy environments. Small enrollment numbers prohibit definitive conclusions, but results suggest high user confidence in ability to make diagnoses in acoustic mode with favorable ratings for ease of use. Doppler mode proved problematic with low median ratings compared to a traditional stethoscope. This may reflect lack of familiarity and experience with an ultrasound modality. Recommendations for improvement are discussed.

15. SUBJECT TERMS

stethoscope, clinical auscultation

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Loraine St. Onge, PhD
UNCLAS	UNCLAS	UNCLAS	SAR	38	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

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Standard Form 298 (Rev. 8/98)
Prescribed by ANSI Std. Z39.18

Acknowledgements

The authors would like to express their sincere gratitude to the following people for their contributions to this project:

- Dr. Arthur Estrada for his leadership and mentorship.
- Ms. Elizabeth Stokes for assistance with all matters administrative.
- Ms. Diana Hemphill and Dr. Loraine St. Onge for their invaluable assistance with literature reviews, manuscript editing, and publication requirements.
- This research study was funded by the Fiscal Year 10 Defense Medical Research and Development Program.

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Introduction

This study was designed to support advanced technology development for clinical auscultation in high noise environments through a clinical assessment (with quantitative analysis) of the diagnostic performance potential of the Noise Immune Stethoscope (NIS). The NIS is a hybrid dual function stethoscope device with both electromechanical acoustic (passive) and ultrasound Doppler (active) modes (see appendix A for technical specifications). It is designed specifically to defeat noise and preserve signal-to-noise (SNR) ratios in loud environments. This permits clinical auscultation in moderate to severe background noise conditions resulting in improved ability to diagnose and subsequently provide medical intervention across the spectrum of care from point of injury through evacuation and levels of care.

Testing and evaluation of the NIS prototype devices to date have verified the ability to function (preserve SNR) in high ambient noise conditions. However, this testing has only included small numbers of research clinicians and small numbers of test subjects (e.g., Gaydos, Williams, Reeves, and Kelley, 2010; Curry, Houtsma, Roller, 2008). The diagnostic potential of the NIS under conditions of *human pathology* remains unknown. Pre-acquisition and fielding research and strategy must include qualitative diagnostic assessment of effectiveness with a clinician cohort representative of future end-user clinicians (e.g., trauma physicians, flight surgeons and flight medics, internists, physician assistants, nurses, medics) under conditions of human pathophysiology (e.g., pneumo- and hemothorax, thoracic trauma, pneumonia, arrhythmias, valvulopathy, heart failure, endotracheal tube misplacement).

Background

The stethoscope (from the Greek *stethos* [chest] and *skopos* [observer]), has been part of the practicing clinician's repository for almost 200 years. Its inventor, Rene Laennec, skillfully noted that the sounds of intrathoracic organs can prove valuable for assessment and diagnosis (Bloch, 1993). Clinical examination by auscultation is fundamental and can be vital to the assessment of patients. It has numerous advantages: inexpensive, rapid, portable, and repeatable.

However, meaningful auscultation is a challenge at best, often impossible, in high ambient noise environments such as the cabin of a medical evacuation helicopter or the open bay of a busy emergency room. There exists a need for a device capable of preserving adequate signal-to-noise ratios and sound discrimination in such conditions (Brady, Gaydos, & Berry, 2010; Houtsma, Curry, Sewell, & Bernhard, 2006a, 2006b, 2007; others). In the military, these high-noise environments can present anywhere from the point-of-injury through medical evacuation, levels of care in theater, and fixed-wing air evacuation. This might include scenarios such as battlefield or aid station stabilizing care (ground evacuation platforms), enroute care aboard a medical evacuation (medevac) helicopter, or inter-theater transport on Air Force aircraft. Permitting the military caregiver the tool of clinical auscultation in all environments enhances ability to diagnose, monitor, and treat across the continuum of battlefield care.

In design of his “ideal” stethoscope, Littmann (1961) noted, “Since the stethoscope is considered the most valuable instrument in the physician’s diagnostic armamentarium, no effort was made to minimize the cost of materials or construction, and on the finest of these were employed.” Yet, traditional stethoscopes, even ones of high quality, only allow successful auscultation up to 80 to 85 decibels (dB) (Houtsma et al., 2006b; Patel et al., 1998). Clearly this is unacceptable for Army medevac helicopters where the noise can reach 120 dB (Houtsma et al., 2007). Likewise, the Air Force has identified a capability gap in aeromedical evacuation (AE) aboard fixed wing aircraft where ambient noise can exceed 85 dB (A. Burns, personal communication, July 31, 2009).

Under the provisions of a Small Business Innovative Research (SBIR) award, Active Signals Technology (AST), Inc. of Linthicum Heights, Maryland, in conjunction with the U.S. Army Aeromedical Research Laboratory (USAARL) developed a “noise-immune” stethoscope (NIS) to address this need (Sewell, 2006). The NIS device consists of a unified hybrid dual-mode design including both an electromechanical acoustic (passive) mode and a 2 to 3 MHz Doppler (active) mode. The enhanced acoustic mode functions similarly to an electronic stethoscope using piezoelectrics. Acoustic information from the body is sensed as vibration energy at the body surface and is converted to very low amplitude electrical signals by the piezoelectric ceramic stack, amplified with low noise electronics and transmitted electrically to speakers in the headset. The integrated active mode consists of an ultrasound transmitter carrier wave with a receiver-transducer integrated into the stethoscope’s head. The carrier wave, reflected back off of patient tissue, is modulated by Doppler Effect (e.g., when auscultating the heart, if the cardiac wall motion is moving towards the receiver, the wave reflected back to the receiver is at a higher frequency). A more thorough treatment of the background and preliminary developmental testing is available elsewhere (Gaydos, et al, 2010; Ahroon, Houtsama, & Curry, 2007; Houtsma et al., 2007; Houtsma et al., 2006b). The device is pictured in figures 1 and 2.

Figures 1 and 2. Dual-mode NIS (A-Scope) with four-button thumb control depicted. (Photos courtesy of AST)

Representative samples of digital recordings for heart sounds in ambient noise conditions are depicted in figures 3 through 6. As an example, the heartbeat signal remains relatively preserved among background noise at 70 dB for both the acoustic mode and the Doppler mode (figures 3 and 4), but lost at the extreme 110 dB (figure 5). However, it remains preserved at 110

dB for the Doppler mode (figure 6; Gaydos et al., 2010). (Digital recordings made using Graphical Interactive Processing of Speech [ver. 2.3] software.)

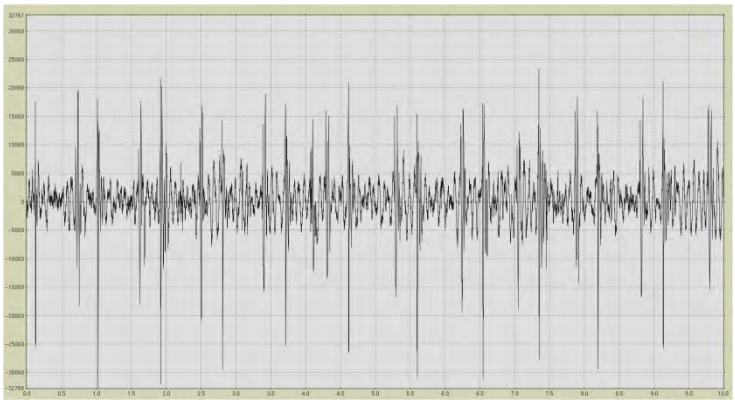

Figure 3. Heart sounds, acoustic mode, 70 dB.

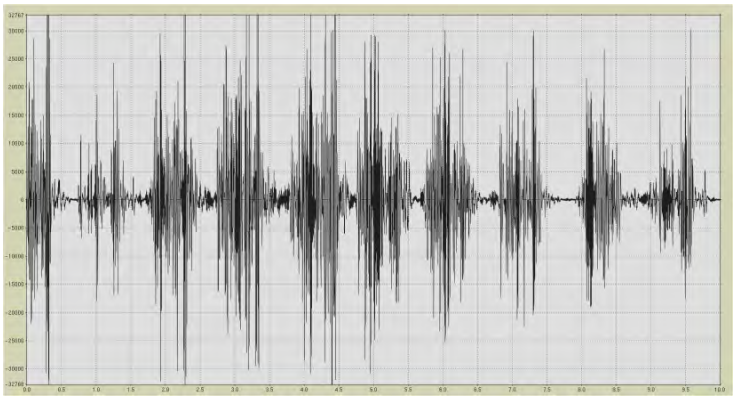

Figure 4. Heart sounds, Doppler mode, 70 dB.

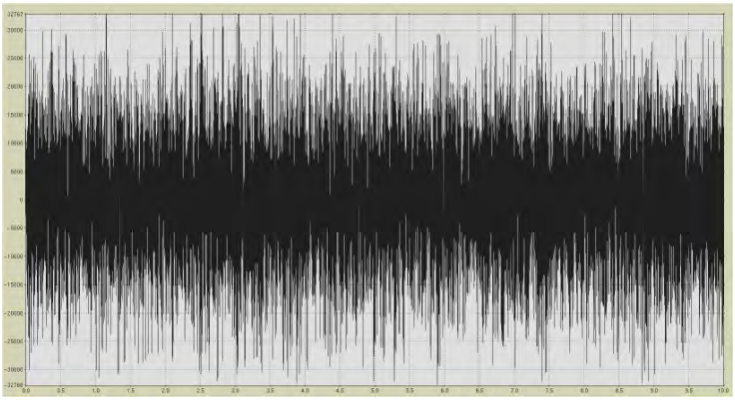

Figure 5. Heart sounds, acoustic mode, 110 dB.

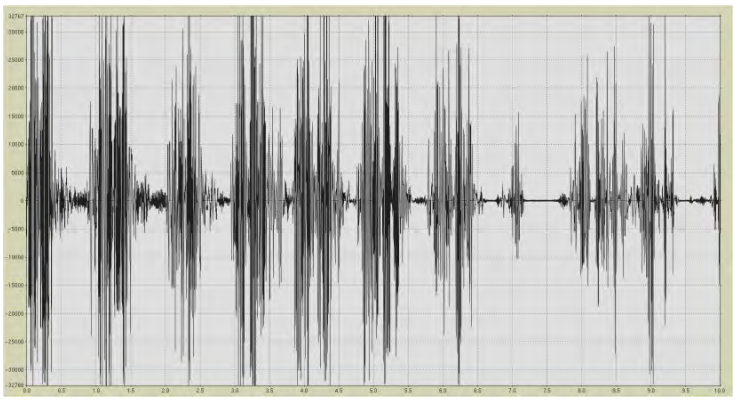

Figure 6. Heart sounds, Doppler mode, 110 dB.

As described previously in the literature, audible returns of the Doppler mode are different from that of a traditional stethoscope by which clinicians are trained to hear. Doppler heartbeat sounds have been described as a “ta-dá-da” three-part rhythm pattern (versus the “lub-dub” of a traditional stethoscope), while normal breath sounds have been described as comparable to bronchial breath sounds or a coarse friction rub. The initial unfamiliarity of these normal physiologic sounds, as well as any clinical retraining necessary to interpret these sounds may be problematic.

USAARL preliminary testing of a prototype NIS device in a reverberant sound chamber demonstrated that the acoustic mode functioned (preserved a signal-to-noise ratio > 0) to an ambient noise environment of approximately 90 dB, whereas the Doppler mode maintained signal-to-noise ratios of approximately 20 dB up to 110 dB of ambient noise (Houtsma et al., 2006b). Subsequent tests in flight confirmed the ability to auscultate both heart and lung sounds in the Doppler mode in a UH-60 helicopter (Houtsma & Curry, 2007). However, the Doppler mode proved somewhat problematic in detecting iatrogenic pulmonary pathology (incremental hemo/pneumothorax) in a swine model (Bushby et al., 2011). The authors noted poor specificity for injury, though it is unclear if the performance was affected by lack of operator training, poor technique, and/or model limitations associated with technical shortcomings of the device and technology.

Advanced prototypes have undergone several revisions and technical improvements (J.M. Sewell & A. Cooke, personal communication, August 27, 2009). Follow-up testing of the production model NIS was conducted in the reverberation chamber at USAARL (Gaydos et al., 2010). Quantitative evaluation confirmed preservation of signal to noise ratio (SNR) > 0 to 90 dB of ambient noise for heart sounds and 100 dB for breath sounds in the acoustic mode. The Doppler mode preserved SNR of 20 dB to 110 dB (testing limit) for both heart and breath sounds. An example of mean SNR recordings for heart sounds in high ambient noise is depicted in Figure 7.

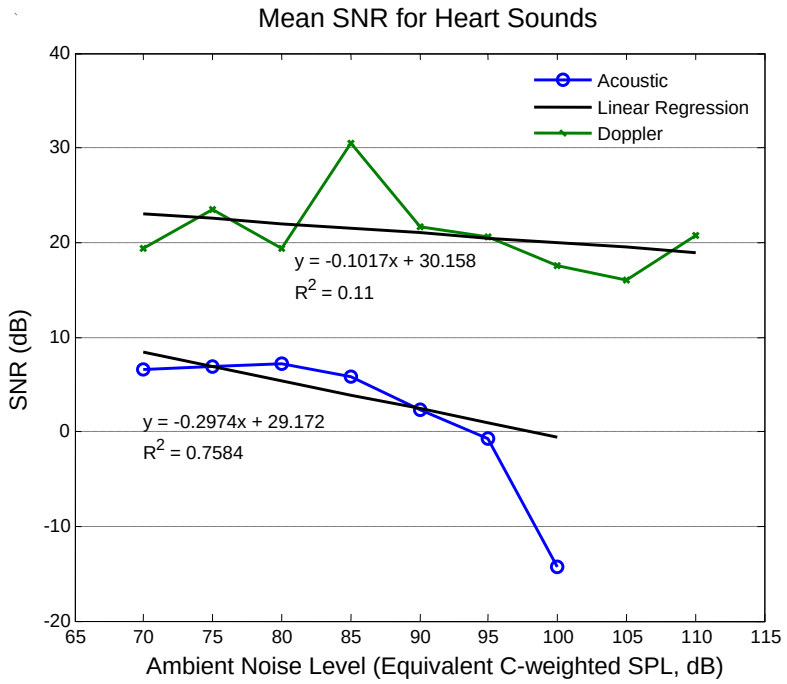

Figure 7. Mean SNR versus ambient noise level (C-weighted dB SPL) for heart sounds. (Note: Heartbeat signals were not audibly discernable at or above 100 dB in the acoustic mode.) (Gaydos, et al., 2010)

In summary, testing and evaluation of the NIS to date has verified the ability to function (preserve SNR) in high ambient noise conditions and provide clinically useful information. However, this testing has only included small numbers of clinicians and normal physiologic sounds. A requirement was identified for a larger-scale qualitative diagnostic assessment of effectiveness with a clinician cohort representative of future end-user clinicians under conditions of *human pathophysiology*. A 2-year Defense Health Program award was secured to address this issue.

This requirement specifies two entities to be addressed: 1) sufficient numbers and diversity of cases of pathophysiology and 2) end-user clinicians operating under real-world conditions in loud ambient noise environments. To address the first issue, a large tertiary-care medical center (MEDCEN) with sufficient medical staff and patient census was chosen with the goal of addressing the variety both "end-users" (physicians of multiple specialties, nurses, technicians, etc.) and variety of pathology. Data collection is currently ongoing for that project at the time of writing this technical report. This current technical report addresses the second issue: data collection by end-user clinicians in real-world, operational deployment conditions with high ambient noise. The venue selected was a U.S. Navy aircraft carrier, the USS Carl Vinson (CVN-70, Figure 8). Of note, the USS Carl Vinson was involved in the historical mission targeting Osama Bin Laden (Heussner, 2011).

Figure 8. USS Carl Vinson Nimitz-class aircraft carrier (www.militaryimages.net).

Carriers are loud—not only during launch and recovery of aircraft on the flight deck, but also from propeller excitation of the ship's structure reradiating as airborne noise, operation of auxiliary equipment, aircraft maintenance, and many other sources (Yankaskas & Fast, 1999). As an example, a query (1994 to 2003) of the U.S. Navy Occupational Exposure Database, Industrial Hygiene Information System showed that the George Washington (CVN-73), another Nimitz-class carrier like the Carl Vinson, reported an 8 hour time-weighted average (TWA) of 84.2 dBA in the medical operations section. To appreciate this significance, Navy regulations require hearing protection when the 8 hour TWA exceeds 84 dBA (U.S. Navy, 2007), meaning that physicians, nurses, and corpsman (according to this survey) should all be wearing hearing protection in the ship's medical bay as they treat patients. Another survey of a different carrier reported an 8 hour TWA of 71.9 dBA—below the threshold of hearing protection requirement, but still very loud. For comparison the sound of a vacuum cleaner at 10 feet is 70dBa (Vanderheiden, 2004).

Utilizing an aircraft carrier also provided other advantages for data collection. By meeting with the ship's medical operations section before port departure, the investigators were able to conduct study and protocol orientation, training with the NIS device (particularly the Doppler feature), address regulatory compliance and study monitoring issues, conduct informed consents, and execute many other administrative tasks without having to travel into a deployed theater.

Methods

The study was conducted as a single center (shipboard), prospective, longitudinal non-randomized qualitative survey. Data collection was conducted aboard the USS Carl Vinson, (CVN-70). CVN-70 is a U.S. Navy Nimitz-class supercarrier with a crew of 3500. Its medical department consists of 47 personnel including a Senior Medical Officer, general surgeon, physical therapist, psychologist, family practitioner, independent duty corpsman, physician assistant, anesthesiologist, radiation health officer, and squadron flight surgeons. Data were collected as an adjunct during routine patient care within the spectrum of clinical duties normally provided by a ship's medical department. Figures 9 through 12 depict the ship's trauma bay, operating room, inpatient ward, and a battle dressing station, respectively.

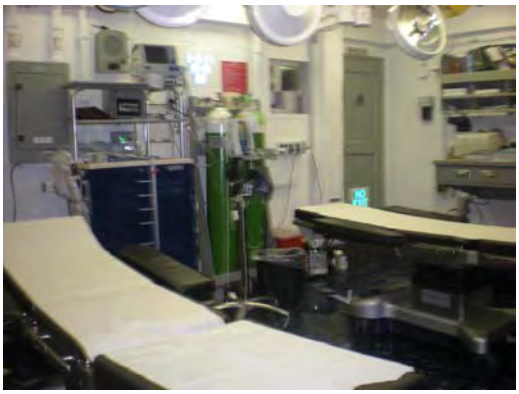

Figure 9. Trauma bay, USS Carl Vinson.

Figure 10. Operating room, USS Carl Vinson.

Figure 11. Inpatient ward, USS Carl Vinson.

Figure 12. Battle dressing station adjacent to the flight deck, USS Carl Vinson.

It is important to note that the NIS was not used to diagnose or direct medical intervention on any patient. Data collection was strictly supplemental to patient care; patient diagnosis and medical treatment was never delayed or otherwise compromised. The investigational NIS was only used after the initial triage, diagnostic, and stabilization measures required for the patient were provided in accordance with established conventional medical and/or surgical practices.

Shipboard clinicians received initial training and study orientation prior to port departure. Training and orientation consisted of study overview, regulatory compliance requirements, data collection procedures, and familiarization with the NIS device. As a novel device, there was no training manual or standard with which to evaluate when users were considered "trained." Following initial familiarization and training, clinicians were considered "trained" when each could comfortably, readily, and repeatedly identify normal heart/lung physiologic sounds with both modes of the device.

The study population consisted of both subject-clinicians and subject-patients, each required to provide signed informed consent. Potential subject-clinicians from the existing pool of shipboard clinicians assigned to the carrier (e.g., physician, physician assistant, nurse practitioner, nurse, medical tech/medic/corpsman) were given the opportunity to volunteer. Subject-patients served as the physiologic signal source(s), and consisted of nonrandomized, nonsequential, adult patients presenting for medical care. There were no requirements or restrictions for patients serving as the physiologic signal source with respect to upper age limit, race, ethnicity, gender, or anthropometrics. There was no active recruitment effort aboard the ship.

Subject-patients, from adult male and female patients presenting to the ship's medical personnel for clinical care, were asked to volunteer. Note that since subject-clinicians were enrolling and conducting informed consent on prospective subject-patient volunteers, the assigned study monitor was required to ensure that all enrolled subject-clinicians completed Human Subject Protection training (e.g., Collaborative Institutional Training Initiative training) prior to the conduct of enrollment and informed consent of subject-patients in accordance with the monitoring plan. The research intervention for the subject-clinician was simply auscultation with the NIS device and completion of the data collection form (appendix B). Data collection

forms corresponded with three conditions: intubation integrity, hemo/pneumothorax, and adventitious/pathologic heart and lung sounds. Qualitative scoring was based on a seven-point Likert scale (1 = “poor” and 7 = “excellent”) with sections available for free-form comments by the clinicians.

At the time of data collection, the NIS was not approved as a medical device by the Food and Drug Administration (FDA). As such, the protocol was approved by the U.S. Army Medical Research and Materiel Command (MRMC) Institutional Review Board (IRB) as an Investigation Device Exemption (IDE) with nonsignificant risk determination (figure 13). The NIS received FDA 510(k) approval in April 2011 (S. Brady, personal communication, April 5, 2011).

Figure 13. NIS labeled as investigational device.

Results

Data were collected over a 7- month operational deployment. Six shipboard clinicians enrolled in the study: one physician (internal medicine/ flight surgeon), one physician assistant (PA), one certified registered nurse anesthetist (CRNA), one critical care nurse (CCN), and two corpsman. However, only the PA, CRNA, and CCN were able to provide data during the course of routine duties aboard the ship. A total of 13 patients (average age of 26.31 years, 1 female and 12 males) gave consent to participate in the study resulting in 18 independent observations made with the NIS. Nine observations were made by the PA, five by the CRNA, and four by the CCN. Nine observations were made (free-form answer) in a patient exam room, five in the operating room, one listed as in a quiet room, and three in the ward.

Intubation integrity

Five observations were made to assess endotracheal (ET) tube placement. Correct confirmatory diagnosis methods included direct laryngoscopy (DL) visualization, traditional stethoscope, and capnography. A Wilcoxin rank-sum test indicated that participants rated their *ability* to auscultate breath sounds bilaterally to confirm ET placement with this device higher in the acoustic mode than in the Doppler mode, $Z = -2.06$, $p = 0.04$. Additionally, participants rated their *confidenc*e in the device to lend towards a correct diagnosis as compared to a traditional stethoscope. Ratings of *confidence* were greater in the acoustic mode than in the Doppler mode

as confirmed by a Wilcoxin rank-sum test, $Z = -2.03$, $p = 0.04$ (figure 14). There were no esophageal intubations.

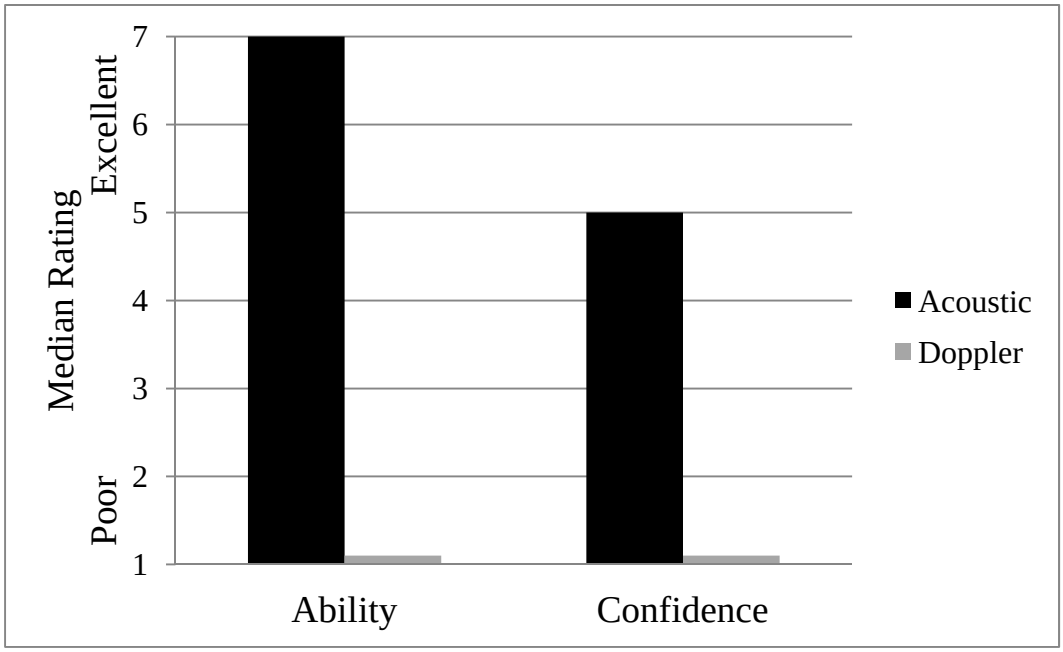

Figure 14. Median ratings of one's ability to detect breath sounds using the device as well as the confidence in the device to make a correct diagnosis in both acoustic and Doppler modes (median for both ability and confidence in the Doppler mode is 1). Note that 1 = "poor" and 7 = "excellent."

Hemo/pneumothorax

There were no observations made to assess hemo/pneumothorax.

Heart /lung sounds pathology

Thirteen observations were made to assess adventitious or pathologic heart/lung sounds. Three patients were diagnosed with bronchitis, eight with pneumonia, one with wheezing, and one with an upper respiratory infection (URI). Correct confirmatory diagnosis methods included traditional stethoscope and chest x-ray. Participants rated their confidence in the use of this device to detect heart/lung sounds compared to a traditional stethoscope. A Wilcoxin rank-sum test indicated that participants rated their *confidenc*e in the use of this device as greater in the acoustic mode than in the Doppler mode as confirmed by a Wilcoxin rank-sum test, $Z = -2.83$, $p = 0.005$ (figure 15). Comments with respect to sound unique to each diagnosis are presented in appendix C.

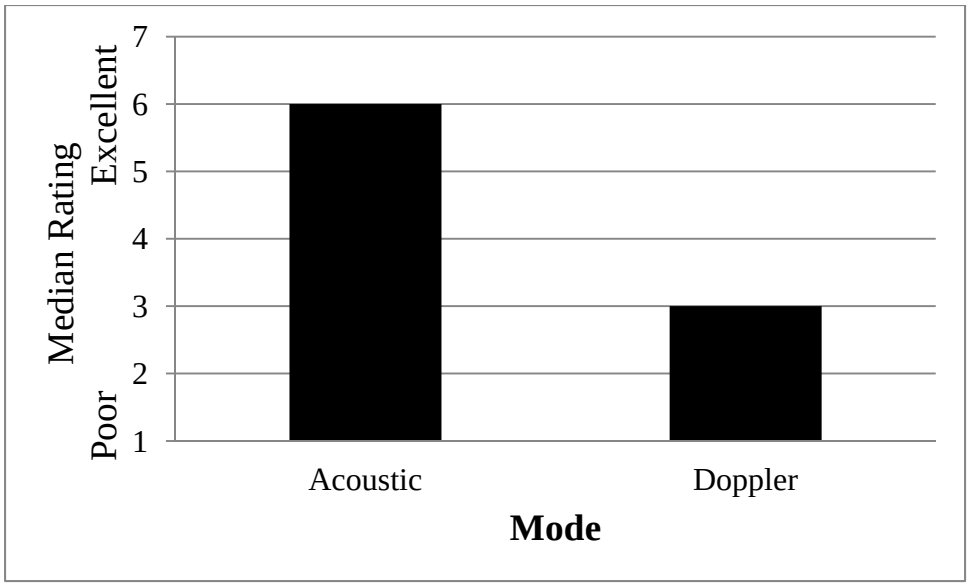

Figure 15. Median ratings of confidence in the use of the device to detect pathologic heart/lung sounds compared to a traditional stethoscope in acoustic and Doppler modes. Note that 1 = "poor" and 7 = "excellent."

Ease of use

For all observations, participants were asked to rate the ease of use of the device compared to a traditional stethoscope on a scale of 1 (difficult) to 7 (easy). A Wilcoxin rank-sum test indicated that participants rated use as easier in the acoustic mode compared to a traditional stethoscope than in the Doppler mode compared to a traditional stethoscope, $Z = -3.37$, $p = 0.001$. A Mann-Whitney U test indicated that no significant differences between rated ease of use between the conditions (tracheal intubation versus heart/lung sounds; figure 16). To assess the ease of use compared to a traditional stethoscope, one-sample Wilcoxin signed rank tests were conducted. The results indicated that in the acoustic mode, participants rated the device to be easier to use than a traditional stethoscope, $Z = 3.04$, $p = 0.002$. The test revealed non-significant results for the Doppler mode.

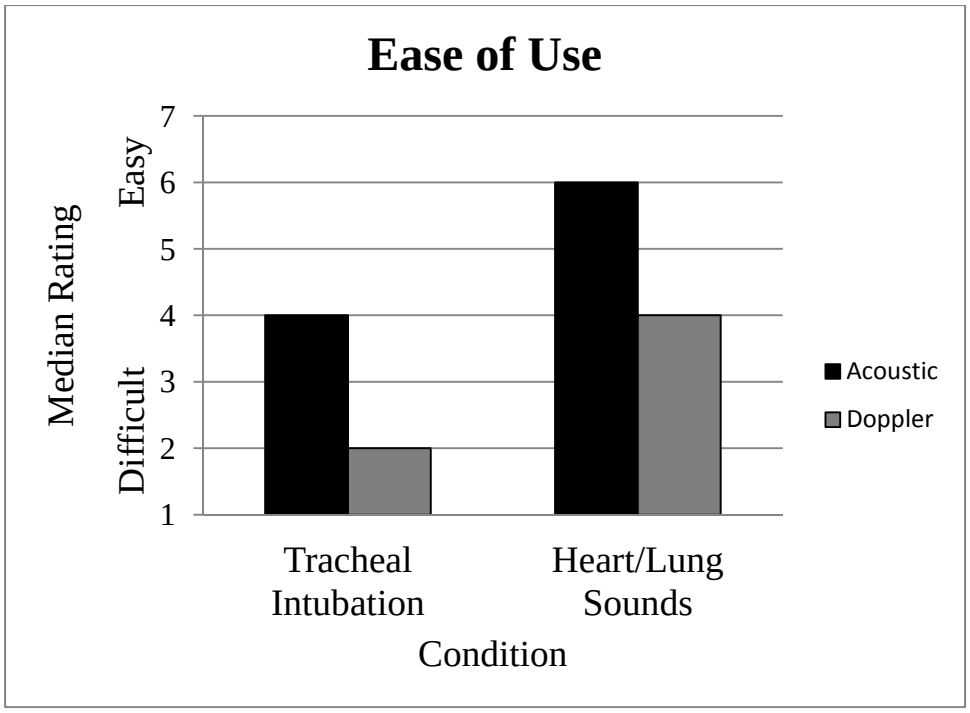

Figure 16. Median ratings of ease of use of the device separated by condition and mode.

Participants rated their impressions of the necessity for three different training methods with the device on a scale from 1 (no) to 7 (yes). Mann-Whitney *U* tests indicated that participants rated the device as more capable to be self-taught for heart/lung sounds than for tracheal intubations, $U = 8.5$, $p = 0.015$, and non-significant results for the other training methods. However, there were significant differences between the rated necessities of the three training methods (based on Friedman's 2-way ANOVA by ranks test, $X^2 = 18.15$, $p < 0.001$). Subsequent comparisons (Friedman's pairwise) indicated that participants rated the training methods of a teaching CD or hands-on learning as a necessity over the option of self-teaching.

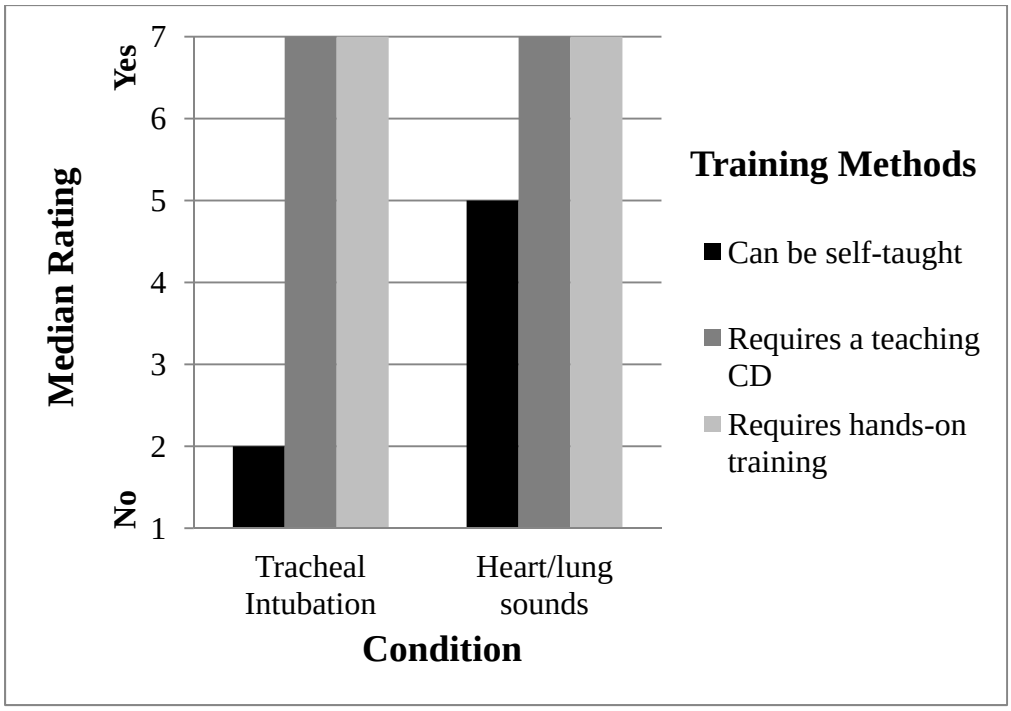

Figure 17. Median ratings of necessity for three different training methods.

Participants were asked to rate the degree to which they felt the requirement of ultrasound gel in the Doppler mode was problematic (1 [problem] to 7 [easy]). A Mann-Whitney *U* test indicated that participants rated the gel as more problematic in the tracheal intubation condition than when detecting heart/lung sounds, $U = 7.00$, $p = 0.009$ (figure 18).

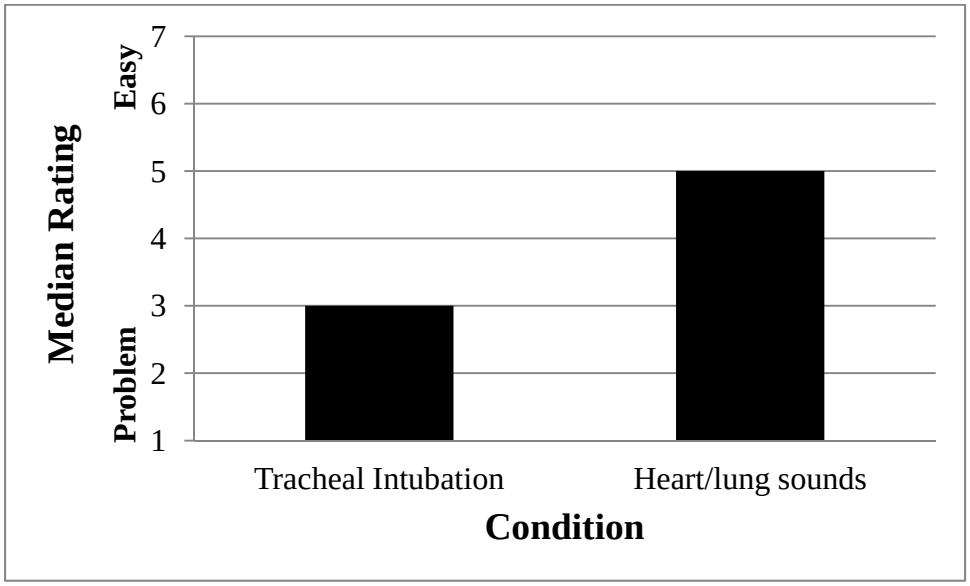

Figure 18. Median ratings of whether the requirement of ultrasound gel was problematic.

Finally, participants were asked to rate overall (both acoustic and Doppler modes) how helpful they felt this device would be to make clinical diagnoses in noisy environments on a scale of 1 (not helpful) to 7 (helpful). A Mann-Whitney *U* test indicated that participants did not significantly rate the device in terms of helpfulness differently in the two conditions (tracheal intubation and heart/lung sounds). To assess the degree to which participants felt this device would be helpful, a one-sample Wilcoxin signed-rank test was conducted (hypothesized median of 4). For the acoustic mode, the results indicated that participants rated the device to be moderately helpful ($Mdn = 5.50$), $Z = 3.04$, $p = 0.002$. For the Doppler mode, the results indicated that participants rated the device to not be helpful ($Mdn = 2.00$), $Z = -1.58$, $p = 0.112$.

Discussion, improvements and future direction

This study was intended to support advanced technology development for clinical auscultation in high noise environments using the NIS. Although providers with a desirable mix of clinical training and experience enrolled, only three different types of clinicians provided data. Despite willingness to support, some providers were simply too busy in daily shipboard operations within a real-world deployed environment to provide observations. Furthermore, the numbers of observations were lower than anticipated. This is also likely attributed to extremely busy providers (no time for adequate patient enrollment, briefing, informed consent, etc.), as well as a shipboard cohort of largely healthy personnel prescreened for preexisting disease prior to deployment. However, the companion to this study, currently in data collection at a large tertiary care medical center, was designed to capture more cases and diversity of pathology. This study was designed to capture clinicians operating in a real-world deployed military environment.

Data collection corresponded with three conditions: intubation integrity, hemo/pneumothorax, and adventitious/pathologic heart and lung sounds. Regarding intubation integrity, all cases were conducted in the operating theater (i.e., no trauma or emergent airway intervention). Recall that this study was approved by the IRB as an IDE. Despite nonsignificant risk determination, no alteration of consent (e.g., retrospective consent following use in the event of trauma or emergency) was permitted. This limited data collection to routine surgical cases whereby the subject-patient could provide prior informed consent. Ability to auscultate breath sounds bilaterally was evaluated as excellent, and confidence in using the device for correct diagnosis was evaluated as better than a traditional stethoscope for the acoustic mode in this setting. The evaluation was very poor for the Doppler mode, however, with comments reflecting difficulty lining up the Doppler in the intercostals and lack of familiarity with the novel audible returns.

There were no observations made for hemo/pneumothorax (see IRB note above). Regarding adventitious/pathologic cardiopulmonary sounds, bronchitis, pneumonia, reactive airways (i.e., wheezing), and URI were represented in the diagnoses. Again, subject-patient accrual rates were low (see above). Clinician confidence to hear the pathologic sounds and make the correct diagnosis was judged better than a traditional stethoscope for the acoustic mode, but worse with Doppler. Doppler-related comments were made to the effect that a change or departure from normal was appreciated with pathology, but difficult to discern disease etiology from the off-nominal returns (e.g., wheeze versus crackles versus rales).

Overall, for all observations, users noted that the acoustic mode was at least as easy to use as a traditional stethoscope or better. There was a prevailing impression that the clinicians lacked confidence in their ability to make correct clinical decisions (e.g., intubation) or diagnoses in the Doppler mode. Although discussed in the Background section, it is worth noting again that the Doppler phenomenon is wholly separate from the passive acoustical physics of a traditional or electronic stethoscope. With respect to training and familiarity, perhaps one should view these results from the perspective of a clinician first learning to use an ultrasound machine. In this study, following initial familiarization, "trained" was considered to be when users could readily and reliable identify normal physiologic sounds in both modes. In reality, the finer clinical aspects of the Doppler probably take much longer to develop just as a young clinician learns to use his traditional stethoscope and is further addressed below.

Unfortunately, given the low numbers of clinicians, patients, and observations, any definitive conclusions from this study alone would be premature (and the lack of previous data or experience with this novel device makes any sort of formal power calculation arbitrary). Results are suggestive that clinicians are confident in their ability to diagnose and direct care with the acoustic mode and it is well-received and easy to use. The acoustic mode has been demonstrated to preserve SNR to approximately 90 dB, and this alone may represent a viable solution in many noisy clinical environments (90 dB comparable to a food blender at 3 feet; Vanderheiden, 2004).

The clinicians found the Doppler mode problematic, which may represent inadequate experience and familiarity using ultrasound modality (albeit with audible return rather than the traditional picture). This is reflected in user median ratings for training methods, as well. Traditional ultrasound has, in fact, been used successfully to diagnose and direct care in extremely noisy environments like a medical evacuation helicopter in combat whereby a traditional stethoscope is rendered useless (e.g., Madill 2010). And, certainly, there are many portable commercial off-the-shelf ultrasound products available. However, without the luxury of years to develop ultrasound skill which most physicians learn over the course of a residency, the intent behind the audible returns (vice traditional ultrasound picture) of the NIS Doppler was to capitalize on its simplicity for use by all clinicians. It has been suggested previously to add a "visual assist" on the back of the Doppler device to provide confidence to the user of signal clarity and integrity (similar to figures 3 through 6) versus movement or reflection artifact. The ability to "visualize" acoustic returns and "match" what is heard, perhaps even compatible with preexisting clinical monitoring devices (e.g., a cardiac monitor), may prove very beneficial to diagnosis confidence in directing care.

"Pitch shifting" and the exploitation of harmonics presents another option for Doppler improvement. A young, healthy human ear can hear a wide range of frequencies from 20 Hertz (Hz) to 20 kHz, though the significant clinical auscultatory frequency range extends only from about 20 Hz to 1 kHz (Dawson, 1964). Heart sounds can range from 20 to 660 Hz, and breath sounds range from 50 to 1 kHz. Unfortunately, the human ear does not "hear" well at low frequencies; this difference in sensitivity is more pronounced at lower frequencies as represented in equal loudness contours (ELC, sometimes known as Fletcher-Munson curves after the originators of work in this area). As an example, a 20 dB sound at 1 kHz is perceived by the listener as the same loudness as a 50 dB sound at the lower frequency of 100 Hz. This decrease

of 30 dB from 1 kHz to 100 Hz is equivalent to a decrease in power of a factor of 300 (also expressed as sound pressure level [SPL]).

Users of the NIS will frequently comment that the low-frequency Doppler return (particularly with breath sounds) can be difficult to appreciate. These comments may, in fact, have their roots in the fact that physiologic sounds lie in a very inefficient portion of the frequency spectrum of human hearing. As an example, current Doppler breath returns barely exceed audibility as depicted in figure 19.

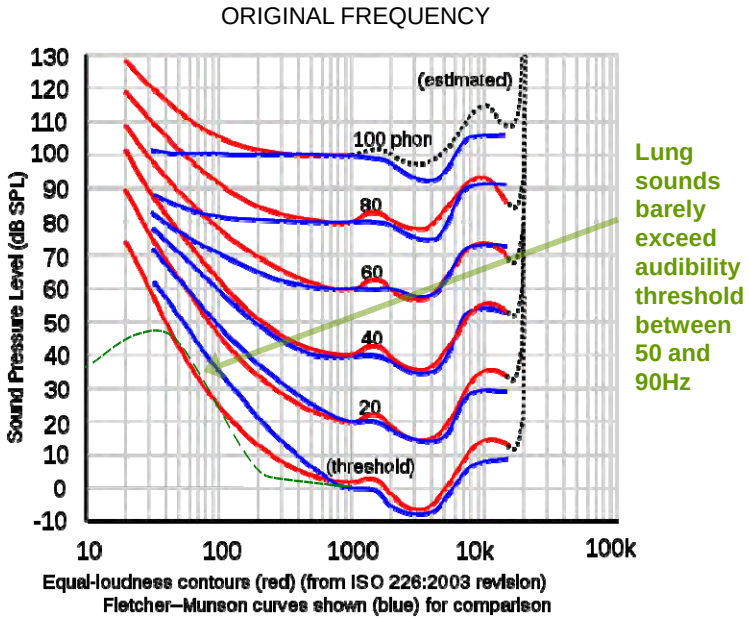

Figure 19: Equal loudness contours (public domain, International Standards Organization, 2003) with Doppler return of lung sounds overlaid (courtesy of AST).

One method of addressing this issue is with simple modulation. For example, modulating the Doppler return with a 500-Hz carrier wave would transform a breath sound of 50 Hz to 550 Hz moving the frequency rightward in the equal loudness diagram. The obvious problem with this approach is that silence (absence of a physiologic Doppler shift return) would still result in an audible return of 500 Hz to the listener. Another more sophisticated and palatable approach would be through “pitch shifting.” By using algebraic multiplication, the spectrum of the sound can be expanded, leveraging emphasis of simple harmonics of the fundamental. Figure 20 demonstrates how multiplying the fundamental at a given SPL can shift the frequency into more efficient regions of the ELCs.

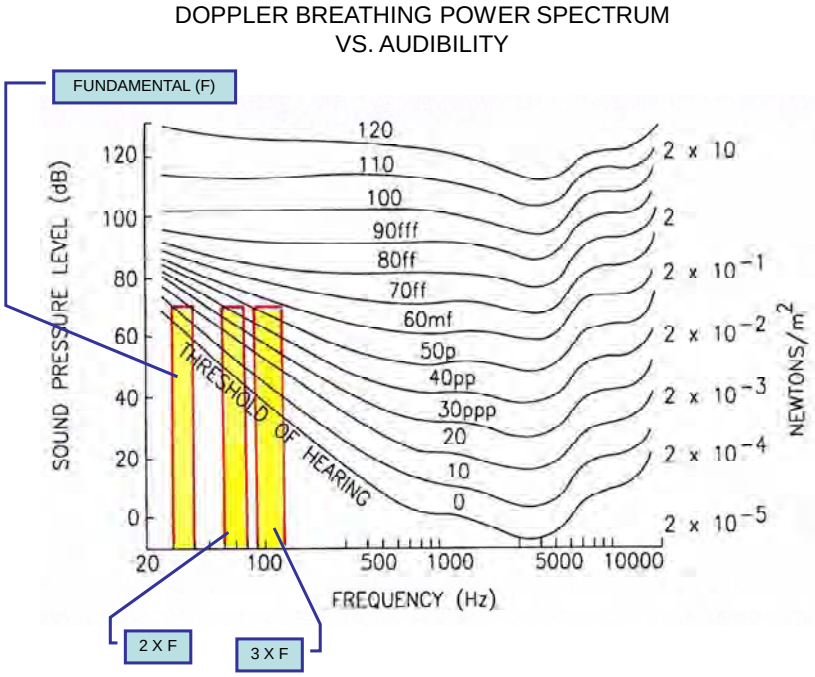

Figure 20: Multiplying fundamentals at a given sound pressure level for Doppler return from the lung (courtesy of AST).

Furthermore, selectively deemphasizing the fundamental and emphasizing second or third order harmonics can create a complex tone which "suggests" the fundamental (perceived by the individual), but the sound actually lacks that specific component (so called "missing" or "suppressed fundamental"). Figure 21 depicts Doppler return of lung sounds at triple frequency. It is still a matter of scientific debate as to how the brain processes the information of harmonics to "fill in the gap" of the fundamental, but this technique of "pseudo low frequency psycho-acoustic sensation" was patented in 1999 (Shashoua & Flotter) and has been employed in commercial acoustics for ten years. This has been a topic of discussion between the primary author and AST and is currently under investigation for NIS application using lab scale instrumentation. Preliminary estimates indicate that this technique can be accomplished without significant increase in battery drain, no appreciable change to the existing housing form of the device, and without signal processing delay (Cooke, 2011). A follow-on study of the practical implementation is recommended to determine if issues of complexity, cost, and signal quality are best accomplished with analog electronics or digital signal processing.

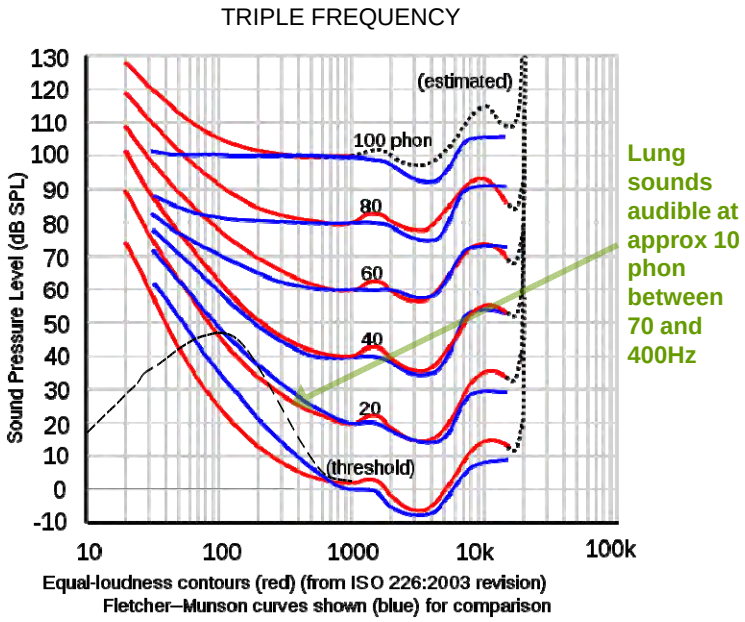

Figure 21: Equal loudness contours (public domain, ISO) with Doppler lung returns overlaid at triple frequency (courtesy of AST).

Another frequent detracting comment from clinicians employing the NIS focuses on the requirement for ultrasound gel when using the Doppler function. Use of gel is commonplace with ultrasound technology to reduce reflections at the skin boundary level. While permissible in a hospital setting, this can be annoying and cumbersome in tactical situations, and the gel tends toward an ineffectual watery consistency in very high ambient temperatures. Interestingly, this was rated as problematic only with endotracheal intubation in this study, most likely due to the fact that observations were made in a non-tactical setting. A potential commercial "off-the shelf" solution might be the employment of gel pads. These are pre-formed, self-contained pads of gel substrate that can be easily applied and removed with a minimal requirement for patient or stethoscope cleanup. Furthermore, pads with a self-stick side can be left in place on the patient at the same anatomic point of auscultation for readily identifiable repeat assessments. This is also currently under investigation including the reproducibility, clarity, and quality of transmitted acoustic returns with pads vice standard gel.

Conclusion

Overall, users evaluated the device to be moderately helpful in making clinical diagnosis and decisions in noisy environments. Small enrollment numbers prohibit definitive conclusions, but results suggest high user confidence in ability to make diagnoses in acoustic mode with favorable ratings for ease of use. Doppler mode proved problematic with low median ratings compared to a traditional stethoscope. This may reflect lack of familiarity and experience with an ultrasound modality. Recommendations for Doppler improvement include a visual assist capability, pitch shifting and exploitation of harmonics for low frequency Doppler returns, and exploration of gel pads.

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Appendix A.

Technical specifications, Noise Immune Stethoscope.

BACKGROUND: A stethoscope is one of the few diagnostic tools available to emergency medical personnel far-forward in the battlefield or in the civilian pre-hospital environment. However, the ability to hear subtle physiological sounds (auscultation) and detect life threatening conditions is frequently compromised by competing noises and commotion at the scene of injury or aboard medical transports.

PRINCIPLES OF OPERATION: Active Signal's stethoscope combats noise intrusion through use of two modes of operation depending on the intensity of background noise:

1. In the presence of relatively benign ambient noise (loud accident scenes, ambulances, emergency rooms, civilian Medevac helicopters, etc.) the device is configured as an amplified electronic stethoscope employing a passive piezoelectric sensor. Noise rejection is imparted by design of the piezoelectric element and mass of the housing.
2. When the ambient sound levels exceed the passive sensing limit, an active Doppler mode is engaged. This transposes the detection of vital physiological sounds from the audio frequency range (used by conventional or electronic stethoscopes) where physiological sounds typically overlap the background noise and hence are swamped out, to ultrasound which puts the measurement into an entirely different frequency band.

DEVICE CONFIGURATION: The dual mode stethoscope design is shown in Figure 1. The top section of the device is the battery compartment, which contains two 1.5V AA-cells. The device is held between the index and middle fingers, with the thumb free to operate a 4-button control panel shown in Figure 2. The bottom section contains the stethoscope sensors and signal-processing electronics. For operation as a passive amplified electronic stethoscope (Mode 1, above), a tall column of piezoelectric ceramic material is used as the sensing element (see Figure 3) contacting the center of the front face. At the top, this column is pressed against the stethoscope's casing. For the active ultrasound-Doppler mode of operation (Mode 2, above), two semicircle-shaped disks, made of piezoelectric material, are embedded in the sensor head, where one functions as a transmitting and the other as a receiving transducer. Details of the mounting geometry, the gap size between the discs and the gap orientation, and also the carrier frequency, determine the width of the sound beam and its penetration depth.

A thumb-operated 4-button control panel allows the device to be turned on (press any button), the signal volume to be set (+ and – buttons in the horizontal plane), and the operating mode to be selected (ultrasound or mechanical). This allows the user to switch between modes during auscultation of a patient without moving the stethoscope on the body.

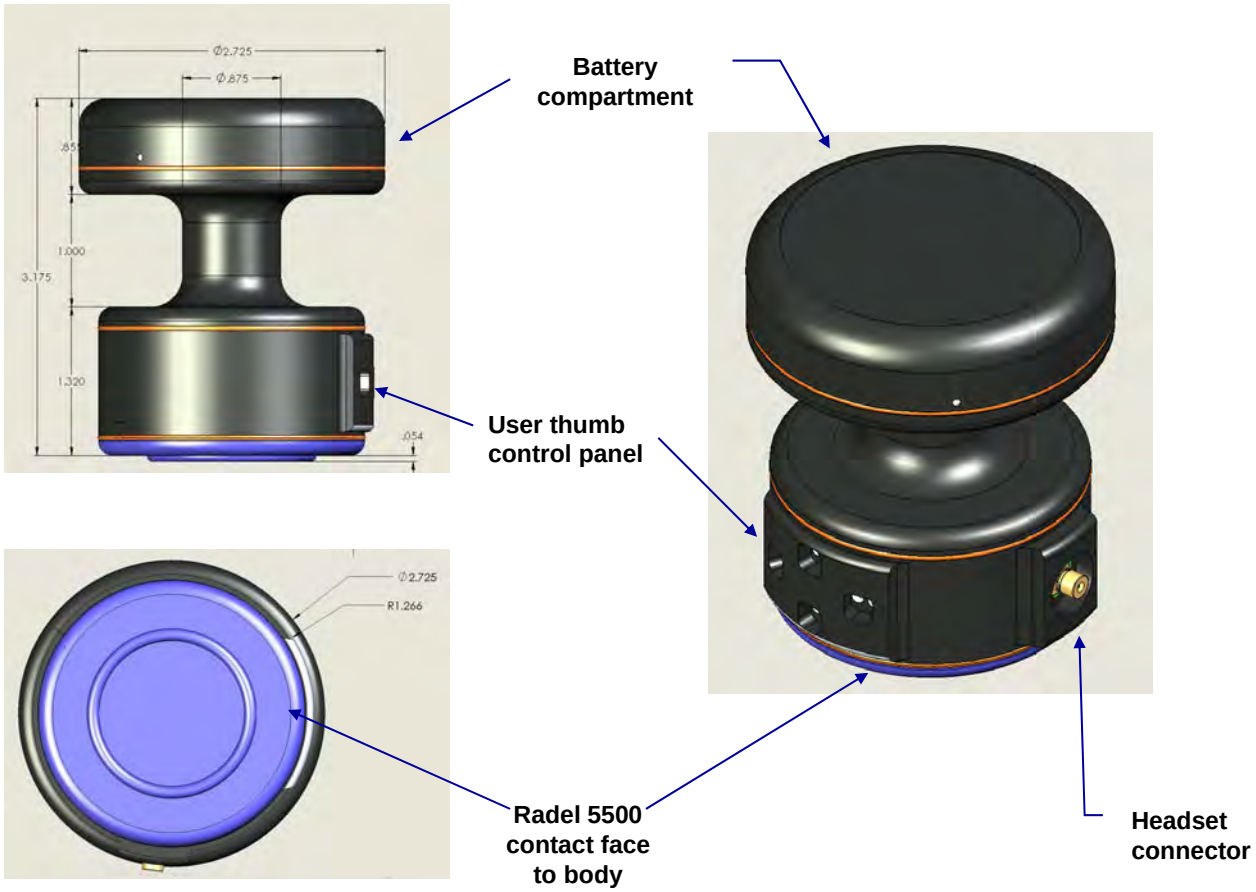

Figure 1. Dual-mode stethoscope design.

Figure 2. Four button control panel for changing mode and volume.

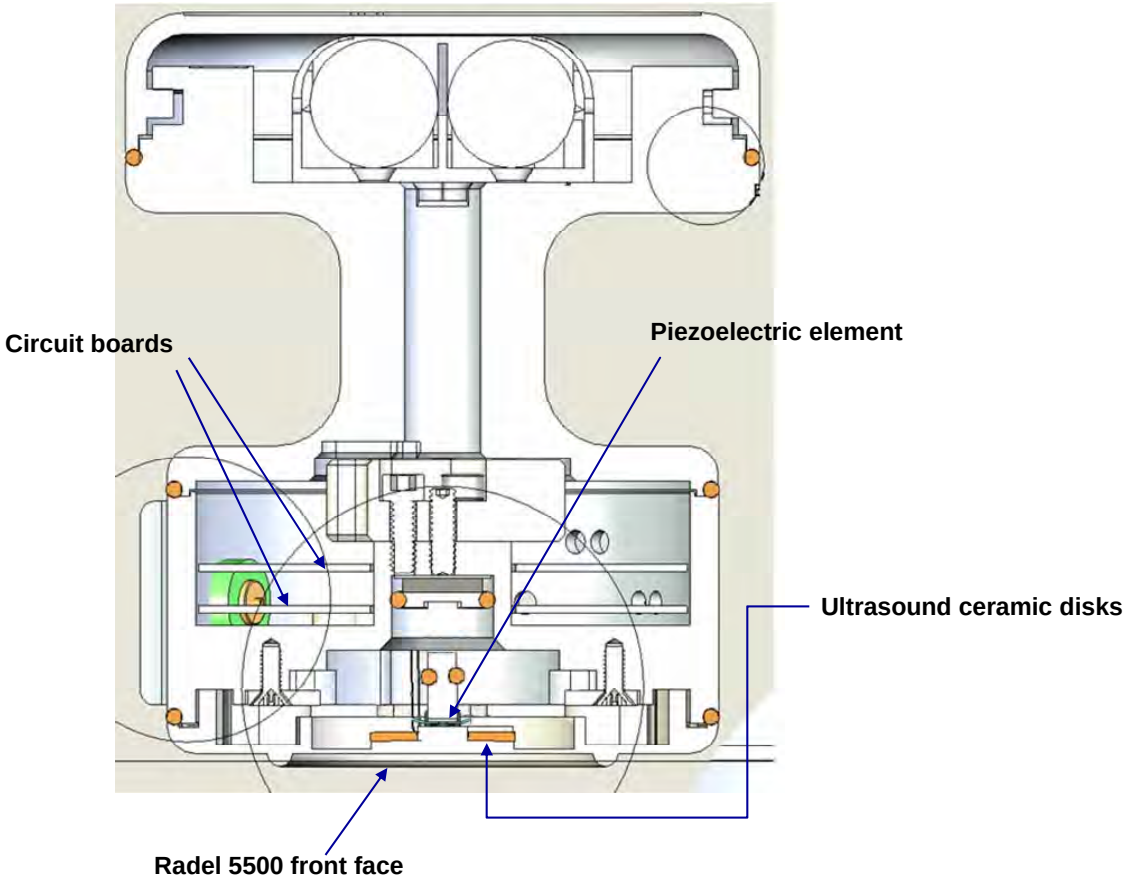

Figure 3. Details of sensor configuration and location of electronic boards.

FEATURES:

Dual 32 step digital volume controls with memory. This allows a comfortable listening level to be set in both modes by the user. Subsequent switching between modes can then be accomplished with minimal user adjustment to allow rapid comparison of acoustic and Doppler auscultation

High efficiency switching power supply and class D audio power amplifier. This extends useful battery life

Auto power off. Enters sleep mode after approximately 10 minutes of user control inactivity

Powered by two AA alkaline batteries.

Simple push button user controls.

Volume Up ↑

Volume Down ↑

Doppler mode button: has 2 functions →

With power off the Doppler mode button switches Power ON

With power on the Doppler mode button selects Doppler Mode

Acoustic mode button: has 2 functions →

With power off the Acoustic mode button switches Power ON

With power on the Acoustic mode button selects Acoustic Mode

SPECIFICATIONS:

Physical dimensions:

Weight:	340 grams (0.75 lb) (including batteries)
Height:	3.2 inches
Diameter:	2.7 inches (largest dimension)

Electrical Specifications:

Typical continuous operation battery life:

Power Off	~9,500 hours (~1 year)
Acoustic mode	~130 hours (~5 days) (minimal audio output)
Doppler mode	~48 hours (~2 days) (minimal audio output)

Audio power amplifier:

Power:	1.4 Watt into 8 Ohm load
THD:	0.19% (typical @ 0.5W)
Efficiency:	84% @ 400 mW
Frequency response:	5 Hz – 20 kHz

Connector: SMB

Doppler Frequency: 1.9 – 2.2 MHz

SIMILARITY TO EXISTING MEDICAL DEVICES: In the passive mode (piezoelectric sensor) the device operates in a similar way to many other amplified electronic stethoscopes on the market today. Acoustic information from physiologic processes is sensed as vibration energy at the surface of the body, converted to very low amplitude electrical signals by the piezoelectric

ceramic, amplified with low noise electronics and transmitted electrically to speakers in the headset. Similarly, the Doppler mode employs substantially the same technology as widely available fetal heart rate monitors for the consumer market. Comparable to other devices that combine acoustic and Doppler modes, the Active Signal device combines the two modes in a compact and convenient self-contained package.

Appendix B.

Data collection forms.

Data Collection Forms

INSTRUCTIONS

1. Complete: **OPERATOR INFO** below, *page 1* (Note: You ***MUST*** be a consented subject-clinician to operate the NIS stethoscope.)

2. Complete: **PATIENT DEMOGRAPHICS** (*page 1)* (Note: Patient ***MUST*** be consented.)

3. Complete: **INTUBATION INTEGRITY** (*page 2)*
   or
   HEMO/PNEUMOTHORAX (*page 3)*
   or
   ADVENTITIOUS OR PATHOLOGIC HEART/LUNG SOUNDS *(page 4)*

4. Complete: **NIS GENERAL COMMENTS & OBSERVATIONS** (*page 5)*

****

STETHOSCOPE OPERATOR INFO

Your Numeric Code (no names): _____ Date of data collection/observation: _____

(**circle one**) Physician PA/NP Nurse Tech/Medic/Corpsman Other: _____

(if Physician, **circle one**) Staff/Attending Fellow Resident

(if Physician, **circle one for specialty**)

Flight Surgeon Family Practice Internal Medicine Anesthesia Surgeon Other: _____

Location aboard ship: _____

Informed consent conducted to patient serving as the physiologic signal source (**circle**): Y N

****

PATIENT DEMOGRAPHICS

(Note: Do ***NOT*** include name, DOB, SSN, or any identifying information.)

Sex (**circle**): M F Age: _____ yrs.

****

INTUBATION INTEGRITY – *TRACHEAL* INTUBATION

Rate your ability to auscultate **BREATH sounds** bilaterally to confirm ET placement (score 1-7)?
ACOUSTIC Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)
DOPPLER Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)

Overall, rate your confidence to use this device to make correct diagnosis of intubation integrity ***compared to a traditional stethoscope*** (4=equivalent)
ACOUSTIC Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)
DOPPLER Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)

Tracheal intubation diagnosis was made/confirmed by (**circle all that apply**):
DL visualization traditional stethoscope capnography x-ray other: _____

Mechanism of injury or etiology of medical condition: _____
Notes: _____
_____

Proceed to end of form for general comments.
****

INTUBATION INTEGRITY – *ESOPHAGEAL* INTUBATION

Rate your ability to auscultate **GASTRIC sounds** bilaterally to confirm ET placement (score 1-7)?
ACOUSTIC Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)
DOPPLER Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)

Rate your ability to auscultate ***NO*** **BREATH sounds** to confirm ET placement (score 1-7)?
ACOUSTIC Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)
DOPPLER Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)

Overall, rate your confidence to use this device to make correct diagnosis of esophageal intubation ***compared to a traditional stethoscope*** (4=equivalent):
ACOUSTIC Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)
DOPPLER Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)

Esophageal intubation diagnosis was made/confirmed by (**circle all that apply**):
DL visualization traditional stethoscope capnography x-ray other: _____

Mechanism of injury or etiology of medical condition: _____
Notes: _____
_____

Proceed to end of form for general comments.
****

HEMO/PNEUMOTHORAX

Rate your ability to auscultate **decreased or absent BREATH sounds** as compared to the contra-lateral side for suspected diagnosis of hemo/pneumothorax (score 1-7)?

ACOUSTIC Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)
DOPPLER Mode: (POOR) 1 2 3 4 5 6 7 (EXCELLENT)

Overall, rate your confidence to use this device to make correct diagnosis of hemo/pneumothorax ***compared to a traditional stethoscope*** (4=equivalent):

ACOUSTIC Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)
DOPPLER Mode: (WORSE) 1 2 3 EQUIV 5 6 7 (BETTER)

Actual diagnosis (be as specific as possible [e.g., 25% simple left pneumothorax without rib fracture or other injuries]; if condition was suspected but not found, then so state [e.g., normal]):_____
_____
_____

Diagnosis was made/confirmed by (**circle all that apply**):
traditional stethoscope CXR CT tube thoracostomy other: _____

Mechanism of injury or etiology of medical condition: _____
Notes: _____
_____

Proceed to end of form for general comments.
****

ADVENTITIOUS OR PATHOLOGIC HEART/LUNG SOUNDS

Actual/known subject diagnosis **(circle)**:

Valvulopathy:	AI/AR	AS	PR	PS	VSD
	MI/MR	MS	MVP	TI/TR	TS
Cardiomyopathy:	ischemic	dilated	hypertrophic		restrictive
Pulmonary disease:	acute asthma	pneumonia	CHF		emphysema

Other: _____

Diagnosis was made/confirmed by (**circle all that apply**):

traditional stethoscope CXR CT MRI cardiac cath
formal ultrasound informal/bedside ultrasound (e.g. Sonosite)
Other: _____

Mechanism of injury or etiology of medical condition: _____

Overall, rate your confidence to use this device to hear the adventitious or pathologic sound (e.g. S3, S4, murmur, click, gallop, snap, wheeze, rales, rhonchi, bruit, etc.) and make correct diagnosis (or suspicion) of the known diagnosis ***compared to a traditional stethoscope*** (4=equivalent):

ACOUSTIC Mode:	(WORSE) 1	2	3	EQUIV	5	6	7 (BETTER)
DOPPLER Mode:	(WORSE) 1	2	3	EQUIV	5	6	7 (BETTER)

Describe in detail any ***novel or unique sounds*** that you are able to hear in Doppler mode (compared to a traditional stethoscope) for this medical condition: _____
_____
_____
_____

Can you correlate these novel or unique sounds with findings from other diagnostic modalities (e.g., ultrasound)? _____
_____
_____

Notes: _____
_____

Proceed to end of form for general comments.

****

AI/R	aortic insufficiency/regurgitation	MVP	mitral valve prolapse
AS	aortic stenosis	PS	pulmonic stenosis
CHF	congestive heart failure	PR	pulmonic regurgitation
MI/R	mitral insufficiency/regurgitation	TI/R	tricuspid insufficiency/regurgitation
MS	mitral stenosis	TS	tricuspid stenosis
		VSD	ventricular septal defect

NIS GENERAL COMMENTS & OBSERVATIONS

Overall, rate your *impressions of* ***ease of use*** of this device *compared to a traditional stethoscope* (4=equivalent):

ACOUSTIC Mode: (DIFFICULT) 1 2 3 EQUIV 5 6 7 (EASY)
DOPPLER Mode: (DIFFICULT) 1 2 3 EQUIV 5 6 7 (EASY)

Based on your use of the device, rate your *impressions of the* ***necessity for training*** (score 1-7):
I can learn to use this device on my own: (NO) 1 2 3 4 5 6 7 (YES)
This device should come with a teaching CD: (NO) 1 2 3 4 5 6 7 (YES)
This device requires "hands-on" training with an instructor: (NO) 1 2 3 4 5 6 7 (YES)

Rate how obtrusive or problematic you found the ***requirement of ultrasound gel*** in the Doppler mode: (PROBLEM) 1 2 3 4 5 6 7 (EASY)

This device has demonstrated the ability to preserve heart and breath sounds in high noise conditions using healthy volunteers (acoustic mode~90 dB, Doppler mode~110 dB). Based on your experience, to what degree to you feel this device ***could help you make clinical diagnoses and decisions*** in noisy environments (e.g., onboard a medical evacuation helicopter)?
(NOT HELPFUL) 1 2 3 4 5 6 7 (HELPFUL)

Do you have any recommendations for improvement in the design or function of the NIS?____

_____
_____

Notes: _____
_____
_____
_____

Appendix C.

Comments provided regarding heart/lung sounds.

Diagnosis	Comment
Wheezing	“abnormal crescendo sounds”
Bronchitis	“sounds different than normal but couldn't distinguish between rhonchi and wheeze”
Pneumonia	“could tell rhonchi but couldn't hear change for wheeze/crackle”
Bronchitis	“wheeze and rhonchi were diminished with doppler mode, i wouldn't have detected this based on doppler mode”
Pneumonia	“i can hear a change in lung sounds but hard to associate some deep breathing provoked a cough”
Pneumonia	“patient had hair on back this definitely distracts the breath sounds! he had wheeze and crackle which can be differentiated on acoustic mode but not on doppler”
Pneumonia	“pathologic sounds/wheezes and xx sounded like speaker distortions (bass)”
Pneumonia	“crackle were very faint on traditional stethoscope, but not heard with acoustic or doppler mode”
Bronchitis	“a series of 3 noises during inspiration sounded like a speaker wire loose”
Pneumonia	“right upper lobe crackle were like quick rapid noises”

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